

Amendment and Response

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Serial No.: 09/698,412

Confirmation No.: 5638

Filed: 27 October 2000

For: AUTOMATED RESPIRATOR FIT TESTING METHOD AND SYSTEM**REMARKS**

The Office Action mailed 31 March 2004 has been received and reviewed. Claims 40-46 having been added, the pending claims are claims 1-46. Reconsideration and withdrawal of the rejections are respectfully requested.

New Claims 40-46

New claims 40-46 have been presented in this response. Support for new claims 40-46 can be found in the application as filed at, e.g., p. 6, line 27 to p. 7, line 2.

Claims 37 and 38

Applicants respectfully point out that while the Office Action Summary page indicates that claims 1-39 are rejected and the claims are briefly discussed at page 5, lines 13-16 of the Office Action, there is no specific rejection of either claim 37 or claim 38 in the text of the Office Action.

To expedite prosecution, however, Applicants respectfully request that the Examiner consider the arguments presented herein with respect to the other claims if it was the Examiner's intent to reject claims 37 and 38 claims, but those claims were inadvertently omitted from the lists specifically identifying the rejected claims.

Response to Arguments

Applicants respectfully traverse the Examiner's comments that "quantitative" mask test fit subject matter is not patentably distinct from "qualitative" mask test fit subject matter. The Examiner asserted that the difference that Applicants pointed out between a quantitative mask test and a qualitative mask test is "a semantic difference that does not amount to an actual difference, let alone one that can serve as evidence of a patently distinct inventive step over the prior art." Applicants disagree.

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"Qualitative" has to do with the qualities of matter, that is, characteristic elements and features that make something what it is. "Quantitative," on the other hand, has to do with quantity, and measurement, that is, the exact amount of a particular thing or that property of anything that which can be determined by measurement. *See, e.g., Webster's New World College Dictionary, Third Edition, Simon & Schuster, Inc., New York, NY, page 1099 (1988)(attached as Exhibit A).* In other words, a qualitative test provides distinctly different information to a user than does any quantitative test on the same matter, thus the difference between a qualitative mask fit test and a quantitative mask fit test is a substantive difference, not merely a semantic difference.

The 35 U.S.C. §103 Rejections

With respect to the present Office Action in general, the comments provided by the Examiner with respect to the rejections therein contain many different assertions with respect to various specific claims. Applicants note, however, that many of these assertions are based on broad conclusory statements such as, e.g., "a matter of mere obvious and routine choice of design," "the duplication of a known part for a known purpose," "the method steps claimed in the instant application would naturally flow from the device disclosed in the prior art," etc. To the extent such statements are not specifically addressed below, Applicants respectfully traverse any and all such assertions and request that the Examiner provide some basis in the art for such currently unsupported or unspecified assertions.

Further, in support of the rejections of many claims, it is asserted that "the suggested device discloses" the feature or features recited in the claim(s) at issue. Applicants note, however, that a proper *prima facie* case of obviousness requires that the claimed features be disclosed in the cited references, not in a "suggested device" as asserted. Furthermore, in most cases, assertions with respect to the asserted disclosure of the "suggested device" are not supported by any citation to the references on which the rejection is based. For at least these reasons, Applicants respectfully submit that rejections based on the features of the "suggested

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devices" do not meet the standards for a proper case of *prima facie* obviousness and should be withdrawn.

Applicants will, however, address the assertions made regarding many of the claims specifically discussed in the Office Action in an attempt to expedite prosecution of the application.

Burström in view of Fennelly et al.

The Examiner rejected claims 1-8, 12-17, 21-22, 24-27, and 31-36 under 35 U.S.C. §103(a) as being unpatentable over Burström (FOA Report C40208-C1 (C2)) in view of Fennelly et al. ("An Automated Aerosol Generator to Reduce Variability in Qualitative Fit Testing of Respirators," K.P. Fennelly et al., American Journal of Respiratory and Critical Care Medicine, Vol. 159, Supp. #3, pp. PA615 DTD 1999). Applicants respectfully traverse this rejection.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation in the references themselves or the knowledge generally available to one skilled in the art to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the references must teach or suggest all the claim limitations (M.P.E.P §2143).

Burström teaches a tent adapted for use during qualitative fit testing of respirators using tear gas as a testing agent. Because it is not a sealed environment, the concentration of the tear gas within the tent decreases over time as illustrated in Figures 4-7. This leakage, however, is not considered to be a problem because the testing is performed outdoors where the tear gas dissipates rapidly.

Fennelly et al. teach a system for fit testing a respirator on an individual using a volume of solution nebulized by an automated nebulizer in place of a manual nebulizer operated by a fit tester.

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Applicants respectfully submit that the combination of Burström in view of Fennelly et al. does not meet the requirements for a *prima facie* case of obviousness because the cited references do not support the asserted suggestion/motivation to combine the references.

The asserted suggestion/motivation for modifying the tent testing system of Burström with the automated nebulizer of Fennelly et al. is "to insure optimal test aerosol was delivered to the test station." The rejection does not, however, discuss how the asserted combination would insure optimal delivery of test aerosol to each subject in the tent. Nor is there any teaching or suggestion in either reference that would lead one of ordinary skill in the art to think that an automated nebulizer would offer the asserted advantage. For example, the Burström reference itself discusses various sources of test aerosols including "tear gas torch X41, boiling of a tear gas tablet with camping stove (ref. 4), and boiling with a hot plate driven by a car accumulator via a thermostat unit." (Burström, *Translation*, page 4). Burström conspicuously does not mention the use a nebulizer (manual or automated) as a potential test aerosol source.

Furthermore, the nebulizers of Fennelly et al. are designed for use with a single subject, not multiple subjects located in a tent as described in Burström. The automated nebulizers of Fennelly et al. processed less than 1 ml of test solution. In contrast, the Burström test protocols involved a tent with a volume of about 4.5 cubic meters. The Office Action provides no discussion at how or why one of ordinary skill in the art could or would attempt to use nebulizers adapted for use with a single test subject to a system in which an entire tent is to be filled with a test aerosol at a concentration of 200 mg/m³ or more as discussed in Burström.

As a result, the cited references do not support the asserted suggestion/motivation to combine that forms the basis for this obviousness rejection. "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." MPEP § 2143.01, p. 2110-131 (8th Ed., Rev. 2, May 2004) (citing *In re Mills*, 16 USPQ2d 1430 (Fed. Cir. 1990)).

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In view of the above observations, Applicants respectfully submit that a proper case of *prima facie* obviousness has not been established for any of independent claims 1, 21, and 26 because the asserted suggestion/motivation is not supported by the references.

The asserted combination of Burström and Fennelly et al. also do not support a *prima facie* case of obviousness with respect to dependent claims 2-8, 12-17, 22, 24, 25, 27, and 31-36, directly or ultimately dependent from claims 1, 21, and 26. Nonetheless, certain individual sets or groups of claims subject to this rejection are addressed in more detail below.

Claims 4 & 22

With respect to claims 4 & 22, which recite the use of a "set of independent aerosol generators," Applicants note that the basis for this rejection lies in the conclusory assertion that the claimed invention involves "the duplication of a known part for a known purpose." Applicants respectfully disagree. As noted above, "[t]he mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." MPEP § 2143.01, p. 2110-131 (8th Ed., Rev. 2, May 2004) (*citing In re Mills*, 16 USPQ2d 1430 (Fed. Cir. 1990)).

In connection with the rejection of claims 4 & 22, suggestion/motivation for the asserted modification ("to process more personnel for mask test fit more quickly") is not supported by the cited references. In fact, Burström teaches only the use of a single source (boiling a tear gas tablet or using a tear gas torch). Use of multiple tear gas sources (or other test aerosol sources) is not disclosed or suggested, nor is there any discussion that using "a set of independent aerosol generators" would enhance testing throughput - other than unsupported conjecture. It would be just as likely to assume that the use of independent aerosol generators would reduce testing throughput.

The standards for a *prima facie* case of obviousness, however, require that "the examiner must provide evidence which as a whole shows that the legal determination sought to be proved (i.e., the reference teachings establish a *prima facie* case of obviousness) is more probable than

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not." MPEP §2142, p. 2100-129 (8th Ed., Rev. 2, May 2004) (emphasis added). That standard has not been met with respect to claims 4 and 22.

For at least the above additional reasons, Applicants submit that the rejection of claims 4 and 22 does not meet the requirements for a *prima facie* case of obviousness and should be withdrawn.

Claim 25

With respect to claim 25, it is asserted that "the test stations and structure of Burström serve as a 'hood.'" Applicants disagree. Burström teaches only the use of bellows to contain the test aerosol within the tent when a test subject has put their head into the tent. Such a bellows does not constitute a testing hood as is known to those of ordinary skill in the art.

For at least the above reasons, Applicants respectfully submit that claim 25 is patentable over the combination of Burström in view of Fennelly et al. Reconsideration and withdrawal of the rejection of claim 25 are, therefore, respectfully requested.

Claims 16-17

Claim 16 recites the use of a sensitivity aerosol in connection with the fit testing methods of the present invention. It is asserted that Burström discloses the use of sensitivity aerosols. Applicants respectfully disagree. The teachings of Burström involve the delivery of aerosols only while the subjects were wearing masks. Page 5 of the Burström translation describes a "preparatory tightness fit" using banana oil, but does not discuss delivering a test aerosol merely to determine sensitivity as recited in claims 16 and 17.

Furthermore, Applicants submit that the rejections and the assertions provided to support them fail to appreciate the full scope of the claimed invention, namely that these claims are directed to methods of delivering a "sensitivity aerosol" in addition to a test aerosol. Some illustrative embodiments of methods that may fall within the scope of claims 16-20 are described in the specification at, e.g., page 12, line 3 to page 13, line 10. Applicants note that the rejections

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of claims 16 and 17 do not address the delivery of a "sensitivity aerosol" in addition to a test aerosol as recited in these claims.

For at least these reasons, Applicants submit that a proper *prima facie* case of obviousness has not been established with respect to claims 16 and 17. Reconsideration and withdrawal of the rejection of claims 16 and 17 are, therefore, respectfully requested.

Claim 26

Claim 26 is an independent claim that recites a method of remote automated respirator fit testing. For a general discussion of remote administration and its potential advantages, the Examiner is directed to page 2, lines 24-31 of the specification.

In setting forth this rejection, the Office Action fails to identify or discuss how or why one of ordinary skill in the art could or would modify the cited references to reach the recited method. In fact, Burström requires the test administrator to be at the testing location to, e.g., boil the tear gas pellet. Nor do Fennelly et al. either teach or suggest a remote fit test administration.

Rather than being based on the cited references, the rejection of claim 26 is based on conclusory assertions that the method "would naturally flow from the device disclosed in the prior art as noted above" and that "the suggested device is fully capable of being provided at a remote location in multiples for simultaneous operation." Neither of these assertions, however, find any support in the cited references. "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." MPEP § 2143.01, p. 2110-131 (8th Ed., Rev. 2, May 2004) (*citing In re Mills*, 16 USPQ2d 1430 (Fed. Cir. 1990)).

In the absence of any reasoned discussion as to how or why the cited references support a *prima facie* case of obviousness with respect to independent claim 26 and a showing of how or where the cited references disclose any remote test administration, Applicants submit that no *prima facie* case of obviousness can be established.

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With respect to claim 27 (which depends from claim 26) the Office Action includes an assertion that Burström discloses remote operation. *See, e.g.*, Office Action, p. 4, lines 11-14. Applicants note, however, that no particular section of Burström is cited as disclosing remote operation. In fact (as noted above), Burström discloses only on-site testing where the test administrator and the test subjects are all at the same location.

For at least these reasons, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 26 and its dependent claims 27-36.

Claims 6-8 & 38

With respect to claims 6-8, Applicants submit that the asserted obviousness rejections also do not meet the requirements for a *prima facie* case of obviousness. Method claim 6 recites "delivering a selected amount of the test aerosol to each of the test subjects at predetermined intervals using the aerosol generator system." The citation to Burström does not disclose or suggest such a method. Rather, each of the test subjects is exposed to the tear gas in a single dose, not "at predetermined time intervals" as recited in claim 6 (and, thus, claims 7 and 8 which depend from claim 6). This is made clear with reference to the translation provided herewith.

In addition, method claims 8 and 38 recite the delivery of "different selected amounts . . . to at least two of the test stations." The rejection of claim 8 is based on the conclusory assertion that "the suggested device is fully capable of delivering different amounts of aerosol to different test stations/subjects." The rejection of claim 38 is based on a similar conclusory assertion. As discussed above, however, the asserted "suggested device" is not supported by the references. In addition, with respect to these claims in particular, no suggestion/motivation for performing the claimed methods has been identified as required for a *prima facie* case of obviousness. As noted above, "[t]he mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." MPEP § 2143.01, p. 2110-131 (8th Ed., Rev. 2, May 2004) (citing *In re Mills*, 16 USPQ2d 1430 (Fed. Cir. 1990)).

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For at least the above additional reasons, Applicants submit that the rejections of claims 6-8 and 38 do not meet the requirements for *prima facie* obviousness and should be withdrawn.

Claims 2-3, 7, and 34

In connection with the rejection of claims 2-3, 7, and 34, a citation is made to "Appendix c of DA Pam 40-8." Applicants note that no such document has been cited by the Applicants or by the Examiner during prosecution of this application. As a result, Applicants are unable to comment on the accuracy of the assertions made with respect to this reference and respectfully submit that it cannot form the basis for a rejection.

If the assertions with respect to this document and the rejection based thereon are to be maintained, Applicants respectfully request that a copy of the reference be supplied with the next Office communication.

For all of the above reasons, Applicants respectfully submit that the rejections of claims 1-8, 12-17, 21-22, 24-27, and 31-36, as well as any rejection that may be made of claims 37 and 38, do not meet the requirements for proper *prima facie* obviousness. Reconsideration and withdrawal of the rejections are, therefore, respectfully requested.

Burström in view of Fennelly et al. and Pasternack

The Examiner rejected claims 9-11, 18-20, and 28-30 under 35 U.S.C. §103(a) as being unpatentable over Burström (FOA Report C40208-C1 (C2)) and Fennelly et al. ("An Automated Aerosol Generator to Reduce Variability in Qualitative Fit Testing of Respirators," K.P. Fennelly et al., American Journal of Respiratory and Critical Care Medicine, Vol. 159, Supp. #3, pp. PA615 DTD 1999) as applied to claim 1 above, and further in view of Pasternack (DE 26 52 136). Applicants respectfully traverse this rejection.

At the outset, Applicants note that Pasternack does not address any of the deficiencies of the combination of Burström in view of Fennelly et al. as applied to the independent claims from

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which the rejected claims depend. For the reasons discussed above then, Applicants respectfully submit that each of the claims subject to this rejection are patentable. However, Applicants will address specific patentability issues with respect to a number of the claims below.

Claims 9, 19, and 28

Applicants submit that, for the following reasons, a *prima facie* cases of obviousness have not been established with respect to claims 9, 19, and 28. The Examiner asserted that, "the suggested device substantially discloses the instant application's claimed invention, but does not explicitly disclose storage results in a database. However, Pasternack disclose such (See disclosure of element 15 of Pasternack, use/creation of a 'data log')." Applicants disagree.

Claims 9 and 28 recite storing the test feedback in a database while claim 19 recites storing sensitivity feedback in a database. "Test feedback" is recited in claims 1 and 27 (from which claims 9 and 28 depend, respectively) as being received "from the test subject" while "sensitivity feedback" is recited in claim 16 (from which claim 19 depends) as being received "from the test subject." In contrast, Pasternack discloses only a quantitative respirator fit testing method in which no test feedback is required or obtained from any test subject. Instead, only quantitative data based on measurements taken inside the mask is monitored. As a result, any assertion that Pasternack discloses storing feedback from a test subject in a database is simply not supported by the reference itself.

For at least these reasons, Applicants respectfully submit that the rejection of claims 9, 19, and 28 over the combination of Burström/Fennelly et al./Pasternack cannot meet the requirements for a proper case of *prima facie* obviousness.

Claims 18-20

Claims 18-20, all of which depend from independent method claim 16, recite features related to the delivery of a sensitivity aerosol in addition to a test aerosol. Some illustrative embodiments of methods that may fall within the scope of claims 16-20 are described in the

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specification at, e.g., page 12, line 3 to page 13, line 10. Applicants note that the rejection of claims 18-20 does not identify how or why one of ordinary skill in the art would deliver a "sensitivity aerosol" in addition to a test aerosol as recited in claims 18-20.

For at least that reason, Applicants respectfully submit that the rejection of claims 18-20 over the combination of Burström/Fennelly et al./Pasternack cannot meet the requirements for a proper case of *prima facie* obviousness.

Claims 28-30

Claims 28-30, all of which depend ultimately or directly from independent method claim 26, recite various features related to remote automated respirator fit testing.

As discussed above with respect to the rejection of method claim 26 based on Burström and Fennelly et al., the Office Action provides no discussion or analysis sufficient for a proper case of *prima facie* obviousness with respect to remote qualitative fit testing as recited in claim 26 (and, therefore, dependent claims 28-30). Nor does the rejection of claims 28-30 address those deficiencies.

For at least that reason, Applicants respectfully submit that the rejection of claims 28-30 over the combination of Burström/Fennelly et al./Pasternack cannot meet the requirements for a proper case of *prima facie* obviousness.

As discussed above, Applicants respectfully submit that the above rejection of claims 9-11, 18-20, and 28-30 do not meet the requirements for proper *prima facie* obviousness. Reconsideration and withdrawal of the rejection are, therefore, respectfully requested.

Burström in view of Fennelly et al. and Tilley

The Examiner rejected claims 12, 31, and 39 under 35 U.S.C. §103(a) as being unpatentable over Burström (FOA Report C40208-C1 (C2)) and Fennelly et al. ("An automated Aerosol Generator to Reduce Variability in Qualitative Fit Testing of Respirators," K.P. Fennelly

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et al., American Journal of Respiratory and Critical Care Medicine, Vol. 159, Supp. #3, pp. PA615 DTD 1999) as applied to claims 1 and 26 above, and further in view of Tilley (U.S. Patent No. 6,435,009). Applicants traverse this rejection.

Applicants note that the claimed methods include "capturing at least one image of the test station" (claim 12), "capturing at least one image of the at least one test station" (claim 31), and "capturing at least one image of at least one test subject at one of the test stations" (claim 39). Tilley does not teach or suggest such a method.

The Examiner asserted that Tilley disclosed "monitoring of screens 272-282 & 370-380 and 398 and the data depicted on the screen being "captured" in memory, the data log" (Office Action, page 8, lines 3-5, emphasis added). Capturing data that also appears on a screen is not, however, the equivalent of capturing an image of a test station or of an image of at least one test subject at one of the test stations (as recited in claims 12, 31, and 39). Applicants thus respectfully submit that Tilley cannot (together with Burström and Fennelly et al.) form the basis for a proper *prima facie* case of obviousness with respect to claims 12, 31, and 39.

In view of the above, Applicants respectfully submit that claims 12, 31 and 39 are patentable over the combination of Burström in view of Fennelly et al. and further in view of Tilley. Reconsideration and withdrawal of this rejection are, therefore, respectfully requested.

Burström in view of Fennelly et al. and Loedding et al.

The Examiner rejected claim 23 under 35 U.S.C. §103(a) as being unpatentable over Burström (FOA Report C40208-C1 (C2)) and Fennelly et al. ("An Automated Aerosol Generator to Reduce Variability in Qualitative Fit Testing of Respirators," K.P. Fennelly et al., American Journal of Respiratory and Critical Care Medicine, Vol. 159, Supp. #3, pp. PA615 DTD 1999) as applied to claim 22 above, and further in view of Loedding et al. (U.S. Patent No. 5,156,776). Applicants respectfully traverse this rejection.

Claim 23 depends from claim 22. As discussed above, claim 22 is patentable over the combination of Burström and Fennelly et al. Loedding et al. does not address any of the

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deficiencies of the rejection of claim 22. For that reason alone, Applicants respectfully submit that claim 23 is patentable over the combination of Burström in view of Fennelly et al. and further in view of Loedding et al. Reconsideration and withdrawal of the rejection are, therefore, respectfully requested.

Summary

It is respectfully submitted that the pending claims 1-46 are in condition for allowance and notification to that effect is respectfully requested.

The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for

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30 AUGUST 2004
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CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 30th day of August, 2004, at 2:20 p.m. (Central Time).

By: Rachael Gaylin-Gebhardt
Name: Rachael Gaylin-Gebhardt

AUG 30 2004

EXHIBIT
A

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